

PFE ORIGINAL



SDMS DocID 2126340

Roche

April 30, 2008

05-04-2004

Harry R. Steinmetz (3HS62)  
U.S. Environmental Protection Agency, Region III  
1650 Arch Street  
Philadelphia, Pennsylvania 19103

Re: **Follow-up CERCLA 104(e) Letter Requiring Submission of Information, Safety Light Corporation Site.**

Dear Mr. Steinmetz:

This response is submitted by Hoffmann La-Roche responding to a follow-up letter from EPA which is undated. We apologize for the tardiness of this response, and note that your counsel, Ms. Humane Zia was contacted on April 24th to advise that our response was being prepared and would be submitted within one week of the call. This date was acceptable to her.

The specific answers are set forth below as pertains to the Site described in the EPA inquiry, and where noted, there are still ongoing document searches, as your request cites a transaction going back to 1962.

1. Roche is only aware of one transaction involving Safety Light Corporation (SLC), and that is the reclamation of 32 H-3 self-illuminating exit signs in July, 2003. Roche paid SLC \$100 each for these services. See attached documents regarding this transaction. Roche has no knowledge of the relationship between SLC and Isolite, as the attached documents make reference to both entities. Roche also has no first hand knowledge of whether the "licensed facility referenced in the attached November 13, 2003 receipt letter is the same as the "Site" Finally, Roche questions whether these H-3 exit signs are even covered under the definition of hazardous substance for purposes of CERCLA coverage.
2. Roche did not broker or transport any radioactive wastes to the Site. The material referenced above was likely shipped by common carrier to Isolite/SLC, although we have not located any shipping documents specific to this material. These materials would have been shipped using a DOT "hazardous materials" designation, which does not require a special permit by the carrier. Rather the driver of the truck in question



must have an endorsement on his/her Commercial Driver's License allowing such materials.

3. N/A
4. Roche is not aware of using any of the companies listed in #4, but did use Isolite/SLC for exit sign reclamation, as noted in the answer to #1.
5. (a) As noted above, Isolite/SLC was used to reclaim 32 H-3 exit signs in July 2003. These signs may even have been manufactured by Isolite/SLC, but to our knowledge were not purchased directly from them, but rather through safety equipment vendors. After search for and review of relevant documents, Roche has no other information relating to disposal of any wastes at the Site. Roche does keep records as required by the USNRC of radioactive waste disposal, and these have been reviewed in the answer to this question. With regard to radioactive waste disposal, Roche has only utilized licensed disposal sites as far back as our records go. Our primary waste broker was and still is Radiac Environmental Service (formerly Radiac Research Corp.) located at 261 Kent Avenue, Brooklyn, NY 11211 and the disposal sites utilized are/were Chem-Nuclear, Barnwell, SC, US Ecology Inc, Richland, WA, Energy Solutions (formerly Envirocare Inc.) Clive, UT.

(b) The current Radiation Safety Officer (RSO) is Mr. Michael Drzyzga, who has been in this position since 1985. This position is required for all holders of USNRC licenses. The RSO is responsible for the safety and compliance of all uses of licensed radioactive material within Roche. He would be primarily responsible for the disposal of any radioactive waste arising from Roche operations. Mr. Jeffrey Guenther, Asst. RSO, also works with Mr. Drzyzga. His predecessor in this position was Dr. Wesley Van Pelt from 1972-1985. Dr. Van Pelt has an office at (b) (6). His predecessor was Dr. Arnold Liebman from 1968-1972, and his current address is (b) (6). Prior to 1968, we are still searching our files.

(c) Roche has no information about a third party shipping company being utilized for this particular shipment. As stated in #2, these exit signs were likely shipped by common carrier.

(d) See attached documents relating to reclamation of 32 H-3 exit signs in July, 2003.

We have reviewed the journal entry sent along with your inquiry, and this apparent disposal of 20 mCi of Strontium-90 is unknown to us at this time. It is worth noting that the first USNRC license for the Roche site in Nutley was issued in 1958. Due to the nature of Sr-90, we would have to be

specifically allowed by NRC in our license to acquire and handle this material, and after review of our original license, and all revisions since, along with relevant ancillary documents, we see no evidence that Roche was ever authorized to acquire or possess this material. Furthermore, the typical uses of such material in the 1950's and 1960's are inconsistent with the Roche business of producing and selling pharmaceutical and (then) vitamin products. We believe Sr-90 was used in medical devices for cataract surgeries, and in instruments to calibrate radiation detectors. These uses are inconsistent with the business operations of Roche during the time period in question. So, we cannot confirm shipment of this material to SLC, and would contest even having the material in the first place to have sent it to SLC.

(e) In addition to names already mentioned, other involved in the Roche waste disposal program are Dr. Jack Kace, Vice President of Corporate Environmental and Safety Affairs. Former employees were:

James Sederis, deceased

Stephen Marga

(b) (6)

Roy Kucks

(b) (6)

Saulle Critelli

(b) (6)

Theodore Berger

(b) (6)

(f) The reclamation of 32 H-3 exit signs did not require any regulatory approval, and so no regulatory documents are attached.

(g) See attached documents. These are the only documents responsive to the EPA letter.

(h) N/A

(i) N/A Roche has been operating at the same location since approximately 1929.



(j) The author of this letter is John Alexander, and contact information is on letterhead. Mr. Alexander is employed in the Roche Law Department (since 1980), and, among other things, handles all legal aspects of environmental and safety related matters.

(k) These answers were prepared with the primary assistance of Michael Drzyzga, who is a Manager in the Technical Operations Dept, and is the designated Radiation Safety Officer for Roche. He has been employed at Roche since June 28, 1965.

6. None

7. N/A

8. None

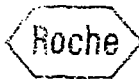
9. N/A

Very truly yours,

A handwritten signature in cursive script, appearing to read "John Alexander".

**FRAGILE**

Hoffman-La Roche Inc.  
340 Kingsland Street  
Nutley, New Jersey 07110-1199



SLC - Isolate Corporation  
ATTN: Health Safety Officer  
4150 - A Old Berwick Road  
Bloomsburg, PA 17815

Control Number:

Shipping Charges:

RmA # 1654 PA - RmA

Shipper's No. 165575

Return Postage Guaranteed

Div	Dept. Code	Account Code	*DEA Registration No.	Date	Packed By	Checked By
2280						
10	5527		N/A	7/18/03		
					Type of Box	

Jeffrey Guenther  
Requested By (Print Clearly)

S-6608  
Extension

Jeffrey M. Guenther  
Authorized Signature

Product Code	Quantity	Pkg. Size	Description	Lot No.
	4-Boxes		32 H-3 Exit Signs for disposal Radioactive Material, excepted package - instruments or articles UN 2911, H-3 No Label Required Roche Emergency Number 800-82-ROCHE	
Box #1	10 signs	H-3	43062 mCi - 1593 GBq	
Box #2	7 signs	H-3	30333 mCi - 1122 GBq	
Box #3	8 signs	H-3	33583 mCi - 1242 GBq	
Box #4	7 signs	H-3	35631 mCi - 1318 GBq	

\*Products covered by the Comprehensive Drug Abuse Prevention and Control Act of 1970  
Pink/Shipping Dept. Blue/Packing List Yellow/File White/Originator



November 13, 2003

Roche Inc  
Attn: Michael Drzyzga  
340 Kingsland Street  
Nutley, NJ 07110

Dear Mr. Drzyzga:

This letter serves as confirmation that thirty-two (32) exit signs (Rec'd at Safety Light Corp. July 22, 2003) were transferred from your organization to our licensed facility in Bloomsburg, PA. This satisfies your obligation under the Code of Federal Regulations, 10CFR31.5(c)(8). Serial numbers will be sent to the USNRC in a quarterly statement.

If you have any questions, please feel free to contact us at any time. Thank you.

Regards,

A handwritten signature in black ink that reads "Nicole Seydel". The signature is fluid and cursive, with the first name "Nicole" and last name "Seydel" clearly distinguishable.

Nicole Seydel  
Sales Services



Created 6/10/2003

Page 1 of 1

**Fax**

<b>To:</b>	Mr. Jack Kace	<b>From:</b>	Nicole Seydel
<b>Phone:</b>	973-235-5000	<b>Phone:</b>	800-888-5483
<b>Fax:</b>	973-235-7605	<b>Fax:</b>	610-296-8952
<b>Re:</b>	Exit Signs		

**•Comments:**

I handle Sales Services for Isolite Corp and my records show our self-luminous exit signs were purchased in 1992 and 1993. These exit signs require no electricity and are powered by tritium gas. The signs purchased in 1992 and 1993 had a ten year life span and will not meet code requirements at this time. I would like to discuss options you have in the proper disposal and/or replacement of these signs. All pricing extended to you would be factory direct and you would only need to speak with one person for your replacement needs. Please contact me at your earliest convenience so that I may answer any questions you may have and provide you with information about our products. Thank you for your time.



No.	Manufacturer	Serial #	Orig. Act. mCi	Date of Orig. Assay	Date of Calib. (Today's Date)	Time Elapsed (yr)	Rate Constant (ln2/t <sub>1/2</sub> )	Current Activity (mCi)	Total H3 Inventory mCi
1	Safety Light Corp.	A291771	8000	9/1/92	7/18/03	10.88	-0.056341463	4333.272	142608.404
2	Safety Light Corp.	A291751	8000	9/1/92	7/18/03	10.88	-0.056341463	4333.272	
3	Safety Light Corp.	A291803	8000	9/1/92	7/18/03	10.88	-0.056341463	4333.272	
4	Safety Light Corp.	A291805	8000	9/1/92	7/18/03	10.88	-0.056341463	4333.272	
5	Safety Light Corp.	A291801	8000	9/1/92	7/18/03	10.88	-0.056341463	4333.272	
6	Safety Light Corp.	A291756	8000	9/1/92	7/18/03	10.88	-0.056341463	4333.272	
7	Safety Light Corp.	A291802	8000	9/1/92	7/18/03	10.88	-0.056341463	4333.272	
8	Safety Light Corp.	A291752	8000	9/1/92	7/18/03	10.88	-0.056341463	4333.272	
9	Safety Light Corp.	A291747	8000	9/1/92	7/18/03	10.88	-0.056341463	4333.272	
10	Safety Light Corp.	A291267	7500	9/1/92	7/18/03	10.88	-0.056341463	4062.443	
11	Safety Light Corp.	A291753	8000	9/1/92	7/18/03	10.88	-0.056341463	4333.272	
12	Safety Light Corp.	A291748	8000	9/1/92	7/18/03	10.88	-0.056341463	4333.272	
13	Safety Light Corp.	A291749	8000	9/1/92	7/18/03	10.88	-0.056341463	4333.272	
14	Safety Light Corp.	A291750	8000	9/1/92	7/18/03	10.88	-0.056341463	4333.272	
15	Safety Light Corp.	A291755	8000	9/1/92	7/18/03	10.88	-0.056341463	4333.272	
16	Safety Light Corp.	A291757	8000	9/1/92	7/18/03	10.88	-0.056341463	4333.272	
17	Safety Light Corp.	A291754	8000	9/1/92	7/18/03	10.88	-0.056341463	4333.272	
18	Safety Light Corp.	A291793	8000	9/1/92	7/18/03	10.88	-0.056341463	4333.272	
19	Safety Light Corp.	A291272	7500	9/1/92	7/18/03	10.88	-0.056341463	4062.443	
20	Safety Light Corp.	A291269	7500	9/1/92	7/18/03	10.88	-0.056341463	4062.443	
21	Safety Light Corp.	A291271	7500	9/1/92	7/18/03	10.88	-0.056341463	4062.443	
22	Safety Light Corp.	A291776	8000	9/1/92	7/18/03	10.88	-0.056341463	4333.272	
23	Safety Light Corp.	A291268	7500	9/1/92	7/18/03	10.88	-0.056341463	4062.443	
24	Safety Light Corp.	A291804	8000	9/1/92	7/18/03	10.88	-0.056341463	4333.272	
25	Safety Light Corp.	A291775	8000	9/1/92	7/18/03	10.88	-0.056341463	4333.272	
26	Safety Light Corp.	A291270	7500	9/1/92	7/18/03	10.88	-0.056341463	4062.443	
27	Safety Light Corp.	A291758	8000	9/1/92	7/18/03	10.88	-0.056341463	4333.272	
28	Safety Light Corp.	A381135	7500	8/1/93	7/18/03	9.97	-0.056341463	4277.380	
29	Unk	Unk	7500	8/1/93	7/18/03	9.97	-0.056341463	4277.380	
30	Shield Source Inc.	B4054	13000	11/1/88	7/18/03	14.72	-0.056341463	5673.048	
31	Shield Source Inc.	B4055	13000	11/1/88	7/18/03	14.72	-0.056341463	5673.048	
32	Isolite Corp	D5101381	20000	10/1/85	7/18/03	17.81	-0.056341463	7334.179	